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EXAMINER
ROSENBERG, S

25M1/0516

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NEW YORK NY 10016

ART UNIT PAPER NUMBER

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DATE MAILED: 05/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 11-13-95 12-8-95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 4, 7, 11-15, 17-19, 22-26, 33-43, 45-55 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 2-5, 8-10, 16, 20-21, 27-32 have been cancelled.
3. ☒ Claims 11-15, 17-19, 22-26, 35, 43-53 are allowed.
4. ☒ Claims 1, 4, 7, 33, 34, 36-42, 54, 55 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. Claims 54 and 55 are rejected under 35 USC § 112, first paragraph as not being supported by the specification as filed.

Claim 54 is directed to a medical apparatus, claiming "living tissue" in lines 1-2 and line 20, and claiming "the skin, tissue or an organ of a patient" in lines 4-5, 6-7, 9, 12-13 and 16. Claim 55 is also directed to a medical application, claiming "living tissue" in lines 1-2 and 9, and claiming a "patient" in lines 6 and 8.

The instant specification as filed has no disclosure related to measuring the living tissue of a patient. There is in the instant specification, one mention of a known problem of measuring, among other things, "the layers of skin and fat which cover muscle tissue" (page 1, lines 22-23), but this disclosure does not specifically teach measuring "living tissue" in a "patient". Note Borsboom (US 4,884,891) which, similar to the instant specification, teaches measuring "muscle tissue, skin" (column 2, line 11), but then notes that this "muscle tissue" is not "living tissue" in a "patient" but rather veal and other meats (column 6, lines 37-39, lines 52-55, lines 66-68 and column 7, lines 7-11). This is evidence that merely disclosing measuring skin and muscle is not a teaching of the specifically medical application of measuring the "living tissue" of a "patient". Further, like the instant specification, in which the disclosure of measuring "the layers of skin and fat which cover muscle tissue" is followed with measuring "the skin of a fruit or

vegetable", Borsboom follows the teaching of measuring "muscle tissue" with a teaching of "milk, cheese, fruit". The coupling of "the skin of a fruit or vegetable" with the teaching of "the layers of skin and fat which cover muscle tissue" would lead the ordinary reader of the instant specification to find the teaching "the layers of skin and fat which cover muscle tissue" to be directed toward meat, as in Borsboom, rather than to the medical use of measuring "living tissue" of a "patient"

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 54 and 55 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hirao et al (US 5,057,695) (hereinafter Hirao).

Claim 54 states:

"Apparatus for non-invasive monitoring of a substance in living tissue, ..."

Hirao shows a non-invasive measure of the degree of oxygen saturation of hemoglobin in blood of in living tissue; see column 1, line 23 through column 2, line 6 for a discussion of measuring oxygen concentration, and column 9, lines 34-35 for a specific teaching that Hirao is measuring oxygen saturation of Hemoglobin. Thus the "substance" of the claim is oxyhemoglobin. The reference also mentions measuring "the concentration of dissolved carbon monoxide, carbon dioxide or the like" (column 9, lines 39-40) which is a teaching of other substances.

"... which apparatus comprises:

a) emitter means capable of emitting electromagnetic radiation, said emitter means being arrangable in use in contact with the skin, tissue of organ of a patient; ..."

In figure 4 of Hirao, light is "irradiated by a single projector 2" (column 8, line 63). The patient of Hirao et al may be a human being (column 10, line 16); the projector 2 is "arrangable in use in contact with the skin" of the patient; Hirao states that "the light guiding members 21a, 21b, 31 may come contact with the interface 1 of the living body tissue" (column 5, lines 55-57).

"b) first radiation detection means arrangable in use in contact with the skin, tissue or organ of said patient, said

first radiation detection means being spaced from the emitter means to detect radiation which has been scattered and attenuated by the skin, tissue of organ of the patient;

c) means for producing a first electrical output signal dependent upon the intensity of the radiation detected by the first radiation detection means; ..."

In the embodiment of figure 4 of Hirao, receiver 3b is the first radiation detection means. The detection means may be in contact with the skin of the patient, see column 5, lines 55-57. discussed above.

"d) second radiation detection means arrangable in use in contact with the skin, tissue or organ of the patient, said second radiation detection means being space farther away than said first detection means and be[ing] in a range to detect radiation which has been scattered and attenuated by the skin, tissue or organ of said patient

e) means for producing a second electrical output signal dependent upon the intensity of the radiation detected by the second radiation [detection] means; ..."

In figure 4 of Hirao, 3b is this second radiation detection means. It is, and is clearly intended to be, spaced apart at a distance farther from the emitter means than the first radiation

detection means 3a; the arrangement disclosed in the reference are based upon having two different path lengths through the tissue of the patient; see, for example, column 2, line 47 and column 6, lines 10-14.

"f) processor means providing a quantitative measure of said substance in said living tissue, said quantitative measure being dependent upon the ratio of said first and second output signals."

The analysis of the signals taught in column 7 and 8 of Hirao clearly teach the measure to be obtained is dependent upon the ratio of the two signals; see equations (6), (7) and (8) in column 8, lines 38-46, each of which relates the "percentage absorption" (a_1 , a_2 , a_3) to a ratio of the two signals (P_{21}/P_{11} , P_{22}/P_{12} , P_{23}/P_{13}).

The reference also teaches what is claimed in method claim 55; the comments above also apply to claim 55. In figure 4 of the reference, 2 is the emitter with 3a and 3b being the first and second detection means; column 5, lines 55-57 teaches contacting the patient. The reference emits light into the patient and receives light from the two detection means and forms a measure of a substance based on the ratio of the signals from the

detected intensities of the received radiation (column 8, lines 38-46).

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 1, 6, 7, 33, 34, and 36-42 are rejected under 35 U.S.C. § 103 as being unpatentable over the prior art discussed on pages 2-4 of the instant specification and Borsboom (US 4,884,891) in view of Howarth (US 3,994,602) and Hirao et al (US 5,057,695).

The specification, on page 3, states that "typically" in the prior art interactance measurements are made using a "central aperture surrounded a small distance away by a ring aperture" Borsboom shows an arrangement with this structure, with a central aperture 2 and a ring 7 around the central aperture some distance

apart; see figure 4 in particular. The ring of the prior art and of Borsboom are "extended in length" with "the total length of said extended surface area being substantially greater than the mean distance separating" the two areas defining the light path through the material. The arrangement of the prior art in the specification discloses only a single path through the sample.

It is known in the art to measure light passing through a material at two different distances; Borsboom teaches a second path through the object (scattered directly back) and both Howarth (figures 6 and 7) and Hirao et al (figures 2 and 4) teach two different path lengths through the material, neither directly back. It thus would have been obvious to provide means, as in Howarth and Hirao et al, to measure to different distances through the material being tested, because the art recognizes that this is useful. It would have been a straight-forward and obvious manner to do this in an arrangement such as shown by Borsboom of adding a second ring at the desired second distance. Borsboom includes a teaching (column 3, line 61 through column 4, line 1) that

"...a sensor head could be made in which a large number of juxtaposed optical fibers of diameter d is arranged concentrically around a central optical fiber with an increasing radius. Measurements made with such a sensor head gives a good picture of the amount of reflected light that has entered the fibres arranged concentrically in rings, and hence of the light reflection as a function of the distance from the light beamed into the material being investigated..." (emphasis added).

This at least clearly suggests placing fibers in rings (plural) concentrically around the central fiber at different distances.

In figure 4, Howarth shows that placing the light detector or transmitter at an angle to direct the light toward, or detect the light from, the other end of the light path through the material.

Hirao et al shows, in figure 5, that it is a known technique to place the illumination and the receivers on opposite sides of the object being measured.

The use of other arrangements than concentric circles for the illumination and detection areas would be obvious because it is the transmission of light through the material, and not the particular geometry of the light source and detectors, that is of functional importance.

Remarks

6. The interference requested in the papers filed 8 December 1995 is not being declared. 37 CFR § 1.606 requires in part that "an examiner must determine that there is interfering subject matter claimed in the application and the patent which is patentable to applicant". As set forth above the claims 54 and 55 which correspond to the proposed counts are not patentable to applicant. Thus no declaration of an interference is appropriate.

7. Additionally, it is noted that claim 55, and proposed count 2, does not appear to correspond substantially to issued claim 2 of the patent. Claim 2 of that patent requires in part "contacting a patient with said emitter means and said first and second radiation detection means of said apparatus of claim 1". Thus claim 2 of the patent has, as a specific method step, using the specific apparatus of claim 1, which includes the limitation that the first and second detection means are spaced at different distances from the emitter means; claim 2 is thus limited to using apparatus in which there is such difference in spacing. Instant claim 55, and proposed count 2, does not refer to any such apparatus, and, unlike patent claim 2, does not contain the limitation that the two detection means are spaced at different distances from the emitter means. Thus claim 55 and proposed count 2 are substantially broader than patent claim 2.

8. As set forth in previous office actions, claims 11-15, 17-19, 22-26, 35 and 53 are allowable.

9. The amendment to claim 43 has overcome the rejections of that claim, thus claim 43 and claims 45-55 dependent therefrom are allowable.

10. The comments filed 13 November 1995 related to the Borsboom reference have been considered, but have not been found

persuasive. The rejection is not based upon an allegation that the fibers 4 in figure 4 of Borsboom correspond to one end of one of the light paths through the material claimed. The rejection is based upon the fact that Borsboom teaches it is known in the art to measure light which has passed through a material being measured by using an emitter and a detector arrangement in which one is arranged in a concentric arrangement around the other, which Borsboom does teach. It is also known to measure such light passing through a material under test at two different distances through the material; this is shown by Hirao et al and Howarth. It would thus have been obvious to modify Borsboom to measure at two different distances as claimed, with two rings, because it is known to do so as shown by Hirao et al and Howarth. Borsboom also at least suggests rings at different distances, see the discussion of column 3, line 61 through column 4, line 1, in the rejection above.

The remarks filed 13 November 1995, on page 7, argue that "it is clear that illumination passes into the material through a surface defined by the end aperture (diameter D) of the central fiber and is collected by the identical surface area into the same end aperture (diameter D) of the central fiber. Thus, in the case of the path defined by the central fiber, the corresponding illumination and detection areas on the material are not separated...". As set forth above, even if this were correct, it would not affect the rejection, but it is not correct. As can be

seen in figure 4, the "central fiber" is not a single fiber, but a fiber bundle composed of many fibers, some of which carry light to the material being tested and others of which receive light from the surface; none of the fibers, however, both transmit light to the material and receive light from the material. Thus the emitter fibers and the receiver fibers do not contact identical areas of the material and any light detected must have passed out of the emitter fibers into the material, and have been scattered back from the material into the detector fibers; this is the only way light could get into the detector fibers to be detected. Thus any light detected will have entered the material and have been scattered into the detector fibers thereby. So the arrangement shown in figure 4 of Borsboom does have separated illumination and detection areas. The comment in the rejection that "Borsboom teaches a second path through the object", with reference to figure 4, appears correct. The arrangement of figure 4 of Borsboom does not have for the central fiber bundle the surface area of one end of the path through the material "extended in length at substantially constant spacing" as claimed, although Borsboom does show this for the outer ring 7, and the rejection is not based upon any interpretation of which Borsboom in which that reference shows in figure 4 such an "extended" area for the receivers of the central fiber bundle.

11. The argument in the remarks, page 7, that Borsboom is somehow "antithetical" to the claimed invention is not persuasive; Borsboom does teach a light path through the material in the manner of the prior art of instant specification, page 3, lines 17-24. As it is otherwise known to use two different length paths through the material, it would have been obvious to use two concentric rings of the sort taught by the prior art of the instant specification and by Borsboom to make such a known measurement having two different length light paths.

12. Neither Howarth nor Hirao et al were cited for, and have not been applied as showing, either the extended in length areas or the concentric surface areas; this feature is shown by the prior art discussed in the specification and by Borsboom. The rejections are not based upon any allegation or belief that Howarth or Hirao show the extended in length areas or the concentric arrangement.

13. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS

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OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

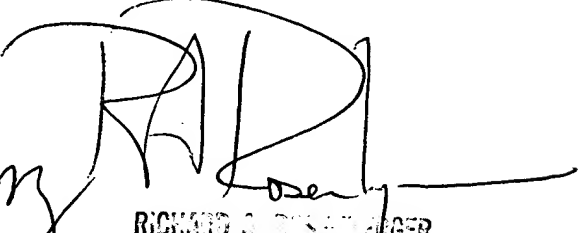
14. Papers related to this application may be submitted to Group 2500 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The fax number is (703) 308-7722.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. A. Rosenberger whose telephone number is (703) 308-4804.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0956.

R. A. Rosenberger
13 May 1996


JIN F. NG
DEPUTY DIRECTOR
GROUP 2500


RICHARD A. ROSENBERGER
EXAMINER
MAY 13 1996